The examiner has required restriction among the following groups of claims:

Group I, including claims 1, 2, 36 and 37, drawn to IFN-γ-inducing protein and compositions comprising it;

Group II, including claims 3-22, drawn to DNA encoding an IFN-γ-inducing protein, corresponding vectors, transformed cells, and recombinant methods of making the protein; and

Group III, including claims 23-35, drawn to a monoclonal antibody, a corresponding hybridoma, and methods of making the mAb, and nominal immunoaffinity purification and immunoassay methods.

The examiner considers the invention to be distinct each from the other. The examiner states that the antibodies of Group III are related to the proteins of Group I insofar as they will specifically recognize the latter, but the products are materially and functionally discrete species. The examiner states that the proteins are not required for the production of the antibodies as the latter may alternatively be generated by immunization against synthetic peptides and that the antibodies may be used independently of the protein as claimed, and that the proteins and antibodies may be made without resort to methods employing the antibodies. The part of the restriction requirement which considers the monoclonal antibodies to be an independent and distinct invention from the protein, is hereby respectfully traversed.

In order to be responsive, applicant hereby elects the claims of Group I, including claims 1, 2, 36 and 37, drawn to an IFN-γ-inducing protein and compositions comprising it. Claims 3-22 of Group II have now been deleted without prejudice toward the filing of a divisional application.

The restriction requirement is respectfully traversed insofar as the monoclonal antibody of claim 23 is considered to be an independent and distinct invention from the protein of claim 1. Claim 23 reads:

> 23. A monoclonal antibody which is specific to the protein of claim 1.

Applicant hereby concedes that, if the protein of claim 1 were available to the prior art (which includes knowledge of its biological activity as set forth in the claim), it would be obvious, within the meaning of 35 USC 103, for one of ordinary skill in the art to make a monoclonal antibody which is specific to such protein. Techniques of raising monoclonal antibodies are well known and the Patent and Trademark Office routinely rejects claims to monoclonal antibodies as being obvious if the protein against which it is specific is known to the prior art.

It should clearly be understood that the present admission is a one-way admission only. Applicant does not concede that if an antibody is known which happens to bind to the protein of claim 1, this would necessarily make the protein of claim 1 obvious or unpatentable. Furthermore, applicant does not concede that <u>all</u> monoclonal antibodies specific for the protein of claim 1

are necessarily obvious. Specific monoclonal antibodies may exist having unexpected properties which would not be obvious from prior art knowledge of the protein to which it is specific. However, in the present case, claim 23 is a broad claim to any monoclonal antibody specific to the protein of claim 1 and the present concession is simply that there are antibodies within the scope of claim 23 which would not be patentable and would be obvious in the sense of 35 USC 103 if the protein of claim 1, including its biological properties, were known to the prior art. Knowing the biological activity of such protein, one of ordinary skill in the art would have been motivated to make a monoclonal antibody for the purpose of immunoaffinity purification or for the purpose of blocking its activity. The techniques for doing so are well known.

In light of the present admission and the provisional election of the protein claims of Group I, a restriction requirement cannot be maintained. If the elected protein claims proceed to issue, any patent issuing on the antibody would have to be subject to an obviousness-type double patenting rejection in view of the above admission. See MPEP §804.II.B.1. relating to double-patenting rejections, which states:

> In determining whether a non-statutory basis exists for a double-patenting rejection, the first question to be asked is - Does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent? If the answer is yes, then "obvious-type" non-statutory double-patenting rejection may be appropriate.

However, such a double patenting rejection cannot be made in light of 35 USC 121. Reference is made to Section 803.01 of the MPEP, where it states:

> Notwithstanding the fact that this section of the statute [35 USC 121] apparently protects the applicant against the dangers that previously might have resulted from compliance with an improper requirement for restriction, IT STILL REMAINS IMPORTANT FROM THE STANDPOINT OF THE PUBLIC INTEREST THAT NO REQUIREMENTS BE MADE WHICH MIGHT RESULT IN THE ISSUANCE OF TWO PATENTS FOR THE SAME INVENTION. [Emphasis original]

See also 37 C.F.R. §1.601(n) defining the concept of patentably distinct inventions from the interference perspective. This rule states:

> Invention "A" is the **same patentable invention** as an invention "B" when invention "A" is the same as (35 USC 102) or is obvious (35 USC 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A".

Here, assuming the protein of claim 1 (invention "B") is prior art to the antibody of claim 23 (invention "A"), the antibody is obvious in light of applicant's admission. Thus, both claims are drawn to the same patentable invention. If they are drawn to the same patentable invention for interference purposes, they should be considered the same patentable invention for all purposes, despite any distinction in the material *per se*. As indicated above, no restriction requirement can be made which would result in the issuance of two patents for the same invention.

MPEP §803 refers to the case of In re Lee, 199 USPQ 108 (Deputy Asst. Comm'r. for Pat's 1978) as requiring that restriction should not be required if there is an express admission that the claimed inventions are obvious over each other within the meaning of 35 USC 103. However, such a two-way admission is not necessary as even the one-way admission presently being made is sufficient to result in two patents directed to the same invention. If an antibody claim in one patent would be obvious from a protein claim in another patent, then the two claims are not patentably distinct and the imprimatur of MPEP §803.01 quoted hereinabove must be invoked.

It should be noted that this identical issue has already been made the subject of a petition to the Commissioner by the undersigned with respect to another case and Deputy Director, Mary C. Lee, confirmed that, in such a circumstance, restriction requirement is not applicable. A copy of that decision is attached hereto. Note particularly where it states:

> At this point it is noted that the fact that there is an admission that the antibody is obvious in view of the peptide but not an admission that the peptide is obvious over the antibody would not change this decision because the Office policy that "no restriction requirements be made which might result in the issuance of two patents for the same invention" would still control.

If claim 23 cannot be restricted from claim 1, then all of claims 23-35 must be examined with the elected claims 1, 2, 36 and 37, as the examiner has already taken the position that claims 24-35 are not patentably distinct from claim 23.

As all of the claims to the non-elected Group II have been deleted and as Group III must be examined with Group I for the reasons discussed above, all of claims 1, 2 and 23-37 presently appearing in this case should be examined in the present application. Withdrawal of the restriction requirement to the extent requested herein and examination and allowance of all the claims now present in the case are therefore earnestly solicited.

Respectfully submitted,

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